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UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

Thomas D. Hoffman
Schering-Plough Corporation
Patent Department (K-6-1-1990)
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Kenilworth NJ, 07033-0530

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,634,697

#28

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,634,697, which claims the active ingredient, ceftibuten dihydrate, of the human drug product CEDAX® (ceftibuten dihydrate- oral suspension) and a method of use of ceftibuten dihydrate, is eligible for patent term extension under 35 U.S.C. § 156, subject to the following requirement of election. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Applicant is required to elect a single patent to be extended under 35 U.S.C. § 156 and a single regulatory review period upon which the extension will be based within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to these time periods.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 27, 1996 (61 Fed. Reg. 44,068). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (1,179) + 1,462
= 2,052 days

Since the regulatory review period began September 28, 1988, after the patent issue date (January 6, 1987), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the limitations of 35 U.S.C. § 156(g)(6) operate to reduce the period of extension determined above. The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment (September 24, 1984) of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year exception of 35 U.S.C. § 156(c)(3) does not operate to further limit the term of the extension in the present situation because fourteen years measured from the date of approval of the approved product is after the expiration date of the patent as extended (i.e., December 20, 2009 is

after October 1, 2009).

It is noted that applicant has also filed applications for patent term extension of U.S. Patent No. 4,812,561 based upon the regulatory review of CEDAX® (ceftibuten dihydrate - capsules) and CEDAX® (oral suspension). No more than one patent may be extended for a regulatory review period of a single product. 35 U.S.C. § 156(c)(4). Furthermore, for a patent to be eligible for patent term extension, the permission for commercial marketing or use must be the first permitted commercial marketing or use of the product under the provision of law under which regulatory review occurred. See 35 U.S.C. § 156(a)(5). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the eligible patent having the earliest date of issuance unless applicant elects a different eligible patent. Therefore, only one of above-identified patent and U.S. Patent No. 4,812,561 can be extended based upon the regulatory review period of either CEDAX® (ceftibuten dihydrate - capsules) or CEDAX® (oral suspension). Furthermore, the extension can only be determined from a single regulatory review period. 35 U.S.C. 156(c). Accordingly, applicant is also required to elect a single regulatory review period upon which the extension will be based. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), an application for patent term extension in the above-identified patent will be granted based upon the regulatory review period of CEDAX® (ceftibuten dihydrate - capsules) and the above-identified application will be dismissed. If U.S. Patent No. 4,634,697 is elected based upon the regulatory review period of CEDAX® (ceftibuten dihydrate - oral suspension), the Commissioner will issue a certificate of extension, under seal, for a period of five years. Extension of time under 37 CFR 1.136(a) is NOT permitted.

If issuance of the certificate of extension occurs, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,634,697
Granted	:	January 6, 1987
Original Expiration Date	:	October 1, 2004
Applicant	:	Yoshio Hamashima
Owner of Record	:	Shionogi & Co., Ltd.
Title	:	CARBOXYALKENAMIDO-CEPHALOSPORINS
Classification	:	514/202

Product Trade Name	:	CEDAX®
Term Extended	:	Five years
Expiration Date of Extension	:	October 1, 2009

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.

Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
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RE: CEDAX® (oral supension)
FDA Docket No.: 96E-0099